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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,876	05/10/2001	Carol Gebert	CG-3	5158

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,876

Applicant(s)

GEBERT ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4, 5, 9-11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al. Leary discloses prior art flow cytometer systems that analyzes cells or particles that are stained with a dye or other labeling compound, excited with a light source and analyzed by photodetectors that convert fluorescence into electrical signals, and then sort the labeled particles according to an electrical charge (column 1, lines 47-65). Leary teaches that such methods are used to detect minimal residual diseases that have a very low cell count (column 2, lines 10-18). Leary does not disclose a means for withdrawing blood from a patient, nor does he disclose a means for maintaining particles in a viable state. However, conventional flow cytometers inherently comprise a means for obtaining fluid for processing. Davidner discloses a blood treatment system with a means for withdrawing blood from a patient via venous cannula 101 and pump 102 that provides a withdrawal force to get blood from the patient (column 4, lines 15-25). The device further provides a UV irradiator 104 that modifies the particles in the tubing system and a hemoconcentrator 106 with a filtration membrane that serves a reservoir means for maintaining the particles in a viable state before returning the

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treated blood to the patient via tubing 107, which removes the treated particles from the hemoconcentrator/reservoir. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the cell labeling and sorting device disclosed by Leary with the cell treating, maintaining, and return device disclosed by Davidner in order to detect, separate, and treat toxic cells, returning good blood to the patient, as taught by Davidner.

3. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al, further in view of US 6,197,593 to Deka et al. The modified Leary device discloses the apparatus as claimed with the exception of using a red-excited dye. Deka discloses the use of a membrane-permanent red-excited dye to distinguish between different types of blood cells, including specific nucleic acid components. Therefore, it would have been obvious to one of ordinary skill in the art to use a membrane-permanent red-excited dye in the cell sorting mechanism disclosed by Leary in order to discriminate between nucleic acid components, as taught by Deka.

4. Claims 15, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al, further in view of US 6,119,031 to Crowley. The modified Leary device discloses the apparatus as claimed with the exception of an implantable analysis system. Crowley discloses an implantable spectrophotometer with a light source and a plurality of light detectors therein. The light detectors convert optical signals into electrical signals to characterize the tissue in question (column 2, lines 44-60). Therefore, it would have been obvious to

one of ordinary skill in the art to make the flow cytometer and pump disclosed by Leary and Davidner of a sufficient size to be implanted in the body in order to minimize the need for large, expensive, and technically challenging analyzers, as taught by Crowley. Furthermore, a change in size is generally recognized as being within the capabilities of someone with ordinary skill in the art.

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,143 to Leary et al in view of US 6,193,681 to Davidner et al, in view of US 6,119,031 to Crowley, further in view of US 6,142,146 to Abrams et al. The modified Leary device discloses the apparatus as claimed with the exception of providing a means to produce electrical power when the pump is actuated. Abrams discloses a device for providing inhalants to a patient with a pump 80 that receives a signal to begin pumping, thereby causing the pump circuit 80 to generate electricity (column 7, lines 7-20). Therefore, it would have been obvious to one of ordinary skill in the art to combine the modified cell sorting system taught by Leary with the electricity-generating pump taught by Abrams in order to cut down on large energy requirements for driving the electrical apparatus, as taught by Abrams.

Response to Arguments

6. Applicant's arguments filed 30 April 2003 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the Leary and Davidner references. However, Leary discloses a cell sorting and labeling device, and Davidner's treatment system treats blood, which is made up of a collection of cells.

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Therefore, the technologies that are applicable to cell sorting and labeling are interchangeable between the two devices, and it would be obvious to one of ordinary skill in the art at the time of invention to use a collection of cells, such as that found in blood and disclosed by Davidner, in a cell-sorting and labeling system, as disclosed by Leary.

It is also proper to combine the Deka reference with the modified Leary/Davidner system, since Deka discloses that his invention is used to distinguish between different types of blood cells. It would have been obvious to one of ordinary skill in the art to use the red dye disclosed by Deka to aid in the sorting of cells in a cell sorting and treating system, as disclosed by Leary and Davidner.

It is further proper to combine the Crowley reference with the Leary/Davidner device, since Crowley discloses an analysis system that analyzes tissue, which is made up of a collection of cells. Crowley discloses an implantable spectrophotometer as a part of his analysis system, and a change in size is generally recognized as being within the capabilities of someone with ordinary skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an implantable spectrophotometer as a part of the cell analysis system disclosed by Leary and Davidner.

It is still further proper to combine the Abrams reference with the Leary/Davidner/Crowley device, since Abrams specifically teaches that large energy requirements for electromechanical devices make the devices large, unwieldy, and unsuitable for portable use. In order to make a smaller, more portable system, Abrams

incorporates a pump that receives a signal to begin pumping, thereby causing the pump circuit to generate electricity, reducing the size and increasing the portability of the device. Since Crowley teaches that the Leary/Davidner device may be implantable, it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate a space and energy-saving means for producing electrical power upon actuation of a pump, as taught by Abrams.

7. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., return of treated particles to the living body) are not recited in the rejected claim 1. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Furthermore, with regard to claim 10 that recites return of treated particles to the living body, Davidner discloses that filtered blood flows through a UV device 104 to a

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hemoconcentrator 106, and back to the patient (see column 4, lines 39-67, column 5, lines 1-15). Therefore, an embodiment of the device does, in fact, return treated particles to the living body, and the instant invention is unpatentable over the combination of the Leary and Davidner disclosures.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.


Ira
July 1, 2003



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700